**UNITED STATES DISTRICT COURT WESTERN DISTRICT OF MISSOURI**

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| ROY BEMISS, QUINTON GOODALL, MAURICE JOSEPH, LAWRENCE ALLEN, LYDIA GRIDLEY, ROBERT KELLEY, SHARON WALLACE, JOSEPH SIRIANNI, and DANIEL LINCOLN, and on behalf of themselves and all others similarly situated,<br><br>*Plaintiffs*,<br><br>v.<br><br>KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; and PHILIPS RS NORTH AMERICA LLC,<br><br>*Defendants*. | **Case No. _____**<br><br>**CLASS ACTION COMPLAINT**<br><br>**DEMAND FOR JURY TRIAL** |

Plaintiffs Roy Bemiss, Lydia Gridley, Daniel Lincoln, Lawrence Allen, Quinton Goodall, Maurice Joseph, Robert Kelley, Sharon Wallace, and Joseph Sirianni ("Plaintiffs"), on behalf of themselves and the Class and State Subclasses, the Class of all others similarly situated as defined below, for their complaint against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), and Philips RS North America LLC ("Philips RS") (collectively, Royal Philips, Philips NA, and Philips RS are "Philips" or the "Defendants"), alleges the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

## I. INTRODUCTION

1. Plaintiffs bring this action on behalf of themselves, and a proposed class and state subclasses of purchasersand users of Continuous Positive Airway Pressure (CPAP) and Bi-Level

Positive Airway Pressure (Bi-Level PAP) devices and mechanical ventilators manufactured by Philips, which contain polyester-based polyurethane sound abatement foam ("PE-PUR Foam").

2. On April 26, 2021, Philips made a public announcement disclosing it had determined there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices it manufactured may degrade or off-gas under certain circumstances.

3. On June 14, 2021, Royal Philips issued a recall in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam, because Philips had determined that (a) the PE-PUR Foam was at risk for degradation into particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain chemicals during operation.[1] Philips further disclosed in its Recall Notice that "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."[2]

4. Philips has disclosed that the absence of visible particles in the devices does not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of the degraded foam reveals the presence of harmful chemicals, including: Toluene Diamine ("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").[3]

5. Prior to issuing the Recall Notice, Philips received complaints regarding the presence of black debris/particles within the airpath circuit of its devices (extending from the

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[1] See Philips Recall Notice attached hereto as Exhibit "A."
[2] *Id.*
[3] Philips Sleep and Respiratory Care Update; Clinical information for physicians, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed September 1, 2021)

device outlet, humidifier, tubing, and mask). Philips also received reports of headaches, upper airway irritation, cough, chest pressure and sinus infection from users of these devices.

6. In its Recall Notice, Philips disclosed that the potential risks of particulate exposure to users of these devices include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing of PE-PUR Foam in these devices include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

7. Philips recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue using their devices and that patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options.

8. In November 2020, Plaintiff Bemiss purchased or obtained a Philips DreamStation CPAP device that he used two to three times per week from November 2020 until the present.

9. Plaintiff Bemiss has or will incur substantial expenses to replace the device. In addition, Plaintiff Bemiss has experienced a runny nose, skin irritation, respiratory issues, inflammatory response, hypersensitivity and headaches during his use of the Philips DreamStation CPAP machine. Since being notified of the recall, Plaintiff has experienced anxiety concerning the potential serious health risks he is facing from possible exposure to off- gassed or degraded PE-PUR Foam in the recalled device.

10. In 2016, Plaintiff Goodall purchased or obtained a Philips DreamStation CPAP device that he used every two days from August of 2016 to August of 2021.

11. Plaintiff Goodall has or will incur substantial expenses to replace the device. In addition, Plaintiff Goodall has experienced high blood pressure, indigestion and headaches during

his use of the Philips DreamStation CPAP machine. Since being notified of the recall, Plaintiff has experienced anxiety concerning the potential health risks he is facing from possible exposure to off- gassed or degraded PE-PUR Foam in the recalled device.

12. In 2018, Plaintiff Joseph purchased or obtained a Philips DreamStation CPAP device that he used daily from January 2018 until August 2021.

13. Plaintiff Joseph has or will incur substantial expenses to replace the device. In addition, Plaintiff Joseph has experienced a runny nose, skin irritation, respiratory issues, inflammatory response, hypersensitivity and headaches during his use of the Philips DreamStation CPAP machine. Since being notified of the recall, Plaintiff has experienced anxiety concerning the potential serious health risks he is facing from possible exposure to off-gassed or degraded PE-PUR Foam in the recalled device.

14. In 2019, Plaintiff Allen purchased or obtained a Philips DreamStation CPAP device that he used nightly from December 2019 to May 2021.

15. Plaintiff Allen has or will incur substantial expenses to replace the device. In addition, Plaintiff Allen has experienced sore throat and difficulty breathing during his use of the Philips DreamStation CPAP machine. Since being notified of the recall, Plaintiff has experienced anxiety concerning the potential health risks he is facing from possible exposure to off- gassed or degraded PE-PUR Foam in the recalled device.

16. In 2020, Plaintiff Gridley purchased or obtained a Philips Trilogy 200 Ventilator that she used two times a day from July 2020 to June 2021.

17. Plaintiff Gridley has or will incur substantial expenses to replace the device. In addition, Plaintiff Gridley has experienced respiratory issues, and inflammatory response during her use of the Philips Trilogy 200 Ventilator. Since being notified of the recall, Plaintiff has

experienced anxiety concerning the potential health risks she is facing from possible exposure to off-gassed or degraded PE-PUR Foam in the recalled device.

18. In 2019, Plaintiff Kelley purchased or obtained a Philips DreamStation CPAP Machine that he used daily from August 2018 to April 2021.

19. Plaintiff Kelly has now incurred substantial expenses to replace the device. In addition, Plaintiff Kelley has experienced respiratory issues, skin irritation, inflammatory response, headache, dizziness, and nausea during his use of the Philips DreamStation CPAP Machine. Since being notified of the recall, Plaintiff has experienced anxiety concerning the potential health risks he is facing from possible exposure to off-gassed or degraded PE-PUR Foam in the recalled device.

20. In 2019, Plaintiff Wallace purchased or obtained a Philips Trilogy 100 Ventilator that she used nightly from October 2019 to July 2021.

21. Plaintiff Wallace has or will incur substantial expenses to replace the device. In addition, Plaintiff Wallace has experienced headaches, dizziness and dry throat during her use of the Philips Trilogy 100 Ventilator. Since being notified of the recall, Plaintiff has experienced Anxiety concerning the potential health risks she is facing from possible exposure to off-gassed or degraded PE-PUR Foam in the recalled device.

22. In 2020, Plaintiff Sirianni purchased or obtained a Philips DreamStation CPAP Machine that he used daily from January 2020 to August 2021.

23. Plaintiff Sirianni has or will incur substantial expenses to replace the device. In addition, Plaintiff Sirianni has experienced skin irritation, respiratory issues and headaches during her use of the Philips DreamStation CPAP Machine. Since being notified of the recall, Plaintiff

has experienced Anxiety concerning the potential health risks he is facing from possible exposure to off-gassed or PE-PUR Foam in the recalled device.

24. In 2018, Plaintiff Lincoln purchased or obtained a DreamStation Auto BiPAP which he used nightly from January 2018 to present.

25. Plaintiff Lincoln has or will incur substantial expenses to replace the device. Plaintiff Lincoln has experienced respiratory issues, headaches and dizziness during his use of the DreamStation Auto BiPAP. Since being notified of the recall, Plaintiff has experienced Anxiety concerning the potential health risks he is facing from possible exposure to off-gassed or PE-PUR Foam in the recalled device.

26. Plaintiffs seek to recover damages based on, *inter alia*, Philips' breach of express warranty, breach of implied warranties, misrepresentations, omissions, and breaches of state consumer protection laws in connection with its manufacture, marketing and sales of devices containing PE-PUR Foam on behalf of themselves and the proposed Class and State Subclasses. In addition, Plaintiffs seek medical monitoring damages for users of Philips' devices identified in the Recall Notice, who are at risk of suffering from serious injury, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic affects.

## II. PARTIES

27. Plaintiff Roy Bemiss is a citizen of Sedalia, Missouri.

28. Plaintiff Quinton Goodall is a citizen of Baltimore, Maryland.

29. Plaintiff Maurice Joseph is a citizen of Plainfield, New Jersey.

30. Plaintiff Lawrence Allen is a citizen of New Port Richey, Florida.

31. Plaintiff Lydia Gridley is a citizen of Payson, Arizona.

32. Plaintiff Robert Kelley is a citizen of Las Vegas, Nevada.

33. Plaintiff Sharon Wallace is a citizen of Mansfield, Ohio.

34. Plaintiff Joseph Sirianni is a citizen of East Grenville, Pennsylvania.

35. Plaintiff Daniel Lincoln is a citizen of Red Bluff, California.

36. Defendant Royal Philips is a Dutch multinational corporation with its principal place of business located in Amsterdam, Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS.[4] Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.[5]

37. Defendant Philips NA is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly owned subsidiary of Royal Philips.

38. Defendant Philips RS is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly-owned

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[4] Philips 2020 annual filing with the SEC, Exhibit 8, https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm (accessed September 1, 2021).

[5] Koninklijke Philips NV 2020 Form 20-F, https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm (accessed September 1, 2021).

subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008.[6]

## III. JURISDICTION AND VENUE

39. This Court has subject-matter jurisdiction pursuant to the Class Action FairnessAct, 28 U.S.C. § 1332(d), because (1) the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, (2) the action is a class action, (3) there are membersof the Class who are diverse from Defendants, and (4) there are more than 100 class members. This Court has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367, because they form part of the same case or controversy as the claims within the Court's original jurisdiction.

40. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) and (c) and 18 U.S.C. § 1965, because Defendants transact business in this District, a substantial part ofthe events or omissions giving rise to one or more of Plaintiffs' claims occurred in this District; because one or more Plaintiffs reside in this District; and because the Defendants caused harm to class members residing in the District.

41. The Court has personal jurisdiction over the Defendants because Defendants conduct substantial business in this District, and the events giving rise to one or more Plaintiffs' claims ariseout of and relate to Defendants' contacts with this District.

42. Stating further and in the alternative, Defendants' affiliations with this District are so continuous and systematic as to render them essentially at home in the forum State.

43. Further, Defendants have transacted business, maintained substantial contacts, purposefully targeted consumers and medical professionals for sales of its devices and/or

[6] Philips announces completion of tender offer to acquire Respironics, WEB WIRE, https://www.webwire.com/ViewPressRel.asp?aId=61199 (accessed September 1, 2021).

committed overt acts in furtherance of the unlawful acts alleged in this Complaint in this District, as well as throughout the United States.

44. The unlawful acts of Defendants have been directed at, targeted, and have hadthe effect of causing injury to persons residing in, located in, or doing business in this District, as well as throughout the United States.

## IV. FACTUAL BACKGROUND

### a. Continuous Positive Airway Pressure Therapy

45. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

46. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles,which can help prevent interruptions in breathing.

### b. Bi-Level Positive Airway Pressure Therapy

47. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

### c. Mechanical Ventilation

48. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

## V. SUBSTANTIVE ALLEGATIONS

49. Philips developed, marketed, and sold a variety of CPAP and Bi-Level PAP respirator devices and mechanical ventilators under its "Sleep & Respiratory Care" segment of its business designed to assist individuals with a number of sleep, breathing, and respiratory conditions, including obstructive sleep apnea, central sleep apnea, complex sleep apnea syndrome,

and Chronic Obstructive Pulmonary Disease (COPD), as well as to assist those individuals requiring invasive and non-invasive ventilators for acute and sub-acute hospital environments. Philips' CPAP and Bi-Level PAP respirator devices and its mechanical ventilatorstypically cost several hundred, if not thousands of dollars. Philips has sold millions of these devices in the United States.

**a. Philips Sleep & Respiratory Care Devices Endangered Users**

50. On April 26, 2021, in its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of PE-PUR Foam Philips used to minimize noise in several CPAP and Bi-Level PAP respirators and mechanical ventilators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature."

51. Seven weeks later, on June 14, 2021, Philips announced a recall of numerous models of CPAP and Bi-Level PAP devices, as well as a variety of its mechanical ventilators "to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices." Specifically, Philip announced that it had determined that the "PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals." In total, Philips announced that "between 3 million and 4 million" devices are targeted in the recall.[7]

[7] Associated Press, Philips recalls ventilators, sleep apnea machines due to health risks, NBC NEWS, https://www.nbcnews.com/business/consumer/philips-recalls-ventilators-sleep-apnea-machines-due- health-risks-n1270725 (accessed September 1, 2021).

52. The list of the devices recalled by Philips (the "Recalled Devices") include:

| **Philips CPAP and Bi-Level PAP Devices Manufactured Before April 26, 2021 Subject to Recall[8]** | |
|---|---|
| **Device Name/Model Type** | **Type** |
| E30 (Emergency Use Authorization) | Continuous Ventilator, Minimum Ventilatory Support, Facility Use |
| DreamStation ASV | Continuous Ventilator, Non-life Supporting |
| DreamStation ST, AVAPS | |
| SystemOne ASV4 | |
| C Series ASV | |
| C Series S/T and AVAPS | |
| OmniLab Advanced Plus | |

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| SystemOne (Q Series) | Non-continuous Ventilator |
| DreamStation | |
| DreamStation GO | |
| Dorma 400 | |
| Dorma 500 | |
| REMStar SE Auto | |

| **Philips Mechanical Respirator Devices Manufactured Before April 26, 2021 Subject to Recall[9]** | |
|---|---|
| **Device Name/Model Type** | **Type** |
| Trilogy 100 Ventilator | Continuous Ventilator |
| Trilogy 200 Ventilator | |
| Garbin Plus, Aeris, LifeVentVentilator | |
| A-Series BiPAP Hybrid A30 | Continuous Ventilator, Minimum Ventilatory Support, Facility Use |
| Philips A-Series BiPAP V30 Auto | |
| Philips A-Series BiPAP A40 | Continuous Ventilator, Non-life Supporting |
| Philips A-Series BiPAP A30 | |

[8] Recall Notice (Exhibit "A" hereto); see also Medical Device recall notification (U.S. only) / field safety notice (International Markets), PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed September 1, 2021).

[9] *Id.*

53. According to Philips, the PE-PUR Foam used in Recalled Devices puts users at risk of suffering from: "irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenicaffects."

54. Philips reported to physicians that PE-PUR Foam particles "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve."

55. Further, Philips reported that "based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment."

56. Philips announced that it has received reports of specific complaints from users of Recalled Devices who suffered from "headache[s], upper airway irritation, cough, chest pressure and sinus infection."[10]

**b. <u>The Health Risks Associated with Use of the Recalled Devices Renders Them Worthless</u>**

57. As a result of the health risks associated with the use of the Recalled Devices, together with Defendants' concealment of these risks from the date they were first reported to Defendants or discovered by Defendants through April 26, 2021, the Recalled Devices have been rendered completely worthless or, at the very least, have been substantially diminished in value.

[10] Recall Notice (Exhibit A hereto).

58. The information described above, including the now-known health risks of Philips CPAP devices, Bi-Level PAP devices and mechanical ventilators, the recall, and the medical warnings and advice issued by Philips, have rendered the Recalled Devices worthless to patients with sleep apnea and respiratory conditions. Individuals not using life-supporting ventilators must immediately discontinue their user of the Recalled Devices or face serious health risks as grave as organ failure or cancer. If they choose to discontinue use of the Recalled Devices they must pay for another expensive device in order to receive effective treatment for their sleep apnea and/or respiratory conditions. Individuals using life-supporting ventilators must seek an alternative treatment before discontinuing use of the Recalled Devices.

59. Recognizing this, Philips issued the following advice to patients using any of the Recalled Devices:

- "**For patients using BiLevel PAP and CPAP devices:** Discontinue use of affected units and consult with physicians to determine the benefits of continuingtherapy and potential risks."

- "**For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps.**"

60. As a result of the above, Plaintiffs and the Class and State Subclasses will have to undertake considerable expense replacing the Recalled Devices.

**c. <u>Philips Unreasonably Delayed its Recall</u>**

61. At no time prior to its Regulatory Update on April 26, 2021, did Philips disclose to purchasers or users of the Recalled Devices that the PE-PUR Foam contained therein may off-gas

or degrade upon use. Similarly, prior to the Update, Philips did not disclose any health risks associated with use of the Recalled Devices.

62. Defendants have not disclosed when they first discovered or received reports from users of their Sleep & Respiratory Care devices "regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[11]

63. At a minimum, as a result of user reports, Defendants were aware of the off- gassing and degradation of the PE-PUR Foam used in the Recalled Devices at some point prior to the recall yet continued to manufacture and sell the Recalled Devices with such awareness. During this period, Defendants unreasonably and unjustly profited from the manufacture and saleof the Recalled Devices and unreasonably put users of the Recalled Devices at risk of development of serious adverse health effects, including organ failure and cancer.

**d. Plaintiffs**

64. Plaintiffs are residents and citizens of the states previously detailed above.

65. Plaintiffs purchased or obtained Recalled Devices as previously detailed above.

66. The manuals accompanying Plaintiffs' Recalled Devices did not contain any language or warnings of health risks associated with use of the device, including irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic effects. Had Defendants informed Plaintiffs of these risks, they would not have purchased or used the Recalled Devices.

67. Without knowing of the health risks associated with use of the Recalled Devices, Plaintiffs used their Recalled Devices regularly to treat sleep apnea as further detailed above.

[11] Recall Notice (Exhibit "A" hereto).

68. As a result of the health risks associated with continued use of these devices and the recall, Plaintiffs' Recalled Devices are now worthless. Plaintiffs have been or will be forced to replace the devices at considerable cost.

## VI. TOLLING AND ESTOPPEL

### a. DISCOVERY RULE TOLLING

69. Plaintiffs and the Class had no way of knowing about Philips'conduct with respect to the health risks associated with the use of the Recalled Devices.

70. Neither Plaintiffs nor any other members of the Class, through the exercise of reasonable care, could have discovered the conduct by Philips alleged herein. Further,Plaintiffs and members of the Class did not discover and did not know of facts that would have caused a reasonable person to suspect that Philips was engaged in the conduct alleged herein.

71. For these, reasons, all applicable statutes of limitation have been tolled by the discovery rule with respect to claims asserted by Plaintiffs and the Class.

### b. FRAUDULENT CONCEALMENT TOLLING

72. By failing to provide immediate notice of the adverse health effects associated with continued use of the Recalled Devices, Philips concealed its conduct and the existence ofthe claims asserted herein from Plaintiffs and the members of the Class.

73. Upon information and belief, Philips intended its acts to conceal the facts and claims from Plaintiffs and members of the Class. Plaintiffs and the members of the Class were unaware of the facts alleged herein without any fault or lack of diligence on their part and could not have reasonably discovered Defendants' conduct. For this reason, any statute of limitations that otherwise may apply to the claims of Plaintiffs or membersof the Class should be tolled.

## VII. CLASS ACTION ALLEGATIONS

74. Plaintiffs bring this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3).

75. Plaintiffs seek class certification on behalf of a class defined as follows (the "Class"):

**NATIONWIDE CLASS:** all person in the United States who, from the beginning of any applicable limitations period through June 14, 2021, purchased or leased one of the Recalled Devices for personal, individual, or home use, a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was manufactured by Philips before April 26, 2021, and recalled by Philips on June 14, 2021.

76. Plaintiffs seek certification on behalf of State Subclasses defined as follows:

**STATE SUBCLASSES**: All persons who were or are citizens of Missouri, Arizona, California, Florida, Maryland, New Jersey, Nevada, Ohio, or Pennsylvania who purchased or used for personal, individual, or home use, a CPAP, Bi-Level PAP, or Mechanical Ventilator device that was manufactured by Philips before April 26, 2021, and recalled by Philips on June 14, 2021.

77. Plaintiffs reserve the right to modify or refine the definitions of the Class and State Subclasses or to seek certification of one or more Subclasses based upon discovery of new information and in order to accommodate any of the Court's manageability concerns.

78. Excluded from the Class and State Subclasses are: (a) any Judge or Magistrate Judge presiding over this action and members of their staff, as well as members of their families; (b) Defendants' and Defendants' predecessors, parents, successors, heirs, assigns, subsidiaries, and any entity in which any Defendants or their parents have a controlling interest, as well as Defendants' current or former employees, agents, officers, and directors; (c) persons who properly

execute and file a timely request for exclusion from the Class or State Subclasses; (d) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (e) counsel for Plaintiffs and Defendants; and (f) the legal representatives, successors, and assigns of any such excluded persons.

79. **Numerosity (Rule 23(a)(1))**. The Class and State Subclasses is so numerous that joinder of individual members herein is impracticable. The exact number of members of the Class and State Subclasses, as herein identified and described, is not known, but sales figures and the Recall Notice indicate that millions of individuals have purchased the Recalled Devices.

80. **Commonality (Rule 23(a)(2))**. Common questions of fact and law exist for each cause of action and predominate over questions affecting only individual Class and State Subclass members, including the following:

- whether Defendants owed a duty of care to Plaintiffs and the Classes;
- whether Defendants knew or should have known that the PE-PUR Foam used for sound abatement posed health risks;
- whether Defendants wrongfully represented that the PE-PUR Foam used for sound abatement in the Recalled Devices was safe;
- whether the Recalled Devices retained any value post-recall;
- whether Defendants wrongfully represented that the Recalled Devices were safe to use;
- whether Defendants wrongfully failed to disclose that the PE-PUR Foam used for sound abatement in the Recalled Devices posed health risks to Recalled Device users;
- whether Defendants' representations and omissions in advertising, warranties, packaging, and/or labeling were false, deceptive, and/or misleading;

- whether those representations and omissions were likely to deceive a reasonable consumer;
- whether a reasonable consumer would consider the presence, or risk of, health risks as a material fact in purchasing one of the Recalled Devices;
- whether Defendants had knowledge that those representations and omissions were false, deceptive, and misleading;
- whether Defendants breached their express warranties;
- whether Defendants breached their implied warranties;
- whether Defendants engaged in unfair trade practices;
- whether Defendants engaged in false advertising;
- whether Defendants' conduct was negligent per se;
- whether Defendants made negligent and/or fraudulent misrepresentations and/or omissions; and
- whether Plaintiffs and the members of the Class and State Subclasses are entitled to actual,statutory, and punitive damages.

81. **Typicality (Rule 23(a)(3))**. Plaintiffs' claims are typical of the claims of the other members of the proposed Class and State Subclasses. Plaintiffs and members of the Class and State Subclasses suffered injuries as a result of Defendants' wrongful conduct, which was uniform across the Class and State Subclasses.

82. **Adequacy (Rule 23(a)(4))**. Plaintiffs' interests are aligned with the Class and State Subclasses they seek to represent. Plaintiffs have and will continue to fairly and adequately represent and protect the interests of the Class and State Subclasses. Plaintiffs have retained competent counsel highly experienced in complex litigation and class actions and the types of

claims at issue in this litigation, with the necessary resources committed to protecting the interests of the Class and State Subclasses. Plaintiffs have no interest that is antagonistic to those of the Class and State Subclasses, and Defendants have no defenses unique to Plaintiffs. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the members of the Class and State Subclasses. Neither Plaintiffs nor Plaintiffs' counsel have any interest adverse to those of the other members of the Class and State Subclasses.

83. **Superiority**. This class action is appropriate for certification because class proceedings are superior to other available methods for the fair and efficient adjudication of this controversy, and joinder of all members of the Class and State Subclasses is impracticable. The prosecution of separate actions by individual members of the Class and State Subclasses would impose heavy burdens upon the Courts and Defendants, would create a risk of inconsistent or varying adjudications of the questions of law and fact common to members of the Class and State Subclasses, and would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests. Class treatment will create economies of time, effort, and expense and promote uniform decision-making.

84. **Manageability.** This proposed class action presents fewer management difficulties than individual litigation, and provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a single court.

85. Class certification, therefore, is appropriate under Fed. R. Civ. P. 23(b)(3) because the above common questions of law or fact predominate over any questions affecting individual members of the Class and State Subclasses, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

86. Stating in the alternative, with respect to the medical monitoring claims set forth here, class certification pursuant to Federal Rule of Civil Procedure 23(b)(2) would also be appropriate.

## CLAIMS FOR RELIEF

## FIRST CLAIM FOR RELIEF

### BREACH OF EXPRESS WARRANTY
### (on behalf of the Nationwide Class or, alternatively, the State Subclasses)

87. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

88. Philips marketed and sold the Recalled Devices into the stream of commerce with the intent that the Recalled Devices would be purchased by Plaintiffs and the Class and State Subclasses.

89. Philips expressly warranted, advertised, and represented to Plaintiffs and the Class and State Subclasses that the Recalled Devices were safe and appropriate for human use.

90. Philips made these express warranties regarding the Recalled Devices' quality and fitness for use in writing through its website, advertisements, and marketing materials, and on the Recalled Devices' packaging and labels. These express warranties became part of the basis of the bargain that Plaintiffs and the Class and State Subclasses entered into upon purchasing the Recalled Devices.

91. Philips' advertisements, warranties, representations, and omissions regarding health risks associated with the Recalled Devices, were made in connection with the sale of the Recalled Devices to Plaintiffs and the Class and State Subclasses. Plaintiffs and the Class and State Subclasses relied on Philips' advertisements, warranties, representations, and omissions regarding the Recalled Devices in deciding whether to purchase and use Philips' Recalled Devices.

92. Philips' Recalled Devices do not conform to Philips' advertisements, warranties, representations, and omissions in that they are not safe, healthy, and appropriate for human use, and pose risks of serious injury and disease, including organ failure and cancer.

93. Philips therefore breached its express warranties by placing Recalled Devices into the stream of commerce and selling them to consumers, when their use posed health risks, had dangerous effects and were unsafe, rendering these products unfit for their intended use and purpose, and unsafe and unsuitable for consumer use as marketed by Philips. These associated health effects substantially impair the use, value, safety of the Recalled Devices, and render them worthless.

94. Philips was aware, or should have been aware, of the toxic or dangerous health effects of the use of the Recalled Devices, but nowhere on the package labeling or package inserts or on Philips' websites or other marketing materials did Philips warn Plaintiffs and members of the Class and State Subclasses that they were at risk of developing adverse health effects as a result of the dangerous PE-PUR Foam used in the Recalled Devices.

95. Instead, Philips concealed the dangerous health effects of the PE-PUR Foam used in the Recalled Devices and deceptively represented that these products were safe, healthy, and appropriate for use. Philips thus utterly failed to ensure that the material representations they were making to consumers were true.

96. The adverse health effects associated with use of the Recalled Devices existed when they left Philips' possession or control and were sold to Plaintiffs and members of the Class and State Subclasses. The dangers associated with use of the Recalled Devices were undiscoverable by Plaintiffs and members of the Class and State Subclasses at the time of purchase of the Recalled Devices.

97. As manufacturers, marketers, advertisers, distributors and sellers of the Recalled Devices, Philips had exclusive knowledge and notice of the fact that the Recalled Devices did not conform to the affirmations of fact and promises.

98. In addition, or in the alternative, to the formation of an express contract, Philips made each of the above-described representations and omissions to induce Plaintiffs and members of the Class and State Subclasses to rely on such representations and omissions.

99. Philips' affirmations of fact and promises and its omissions were material, and Plaintiffs and members of the Class and State Subclasses reasonably relied upon such representations and omissions in purchasing and using the Recalled Devices.

100. All conditions precedent to Philips' liability for its breach of express warranty have been performed by Plaintiffs or members of the Class and State Subclasses.

101. Affording Philips an opportunity to cure its breaches of written warranties would be unnecessary and futile here. Philips was placed on reasonable notice from user reports and its lab testing that the PE-PUR Foam in the Recalled Devices was unsafe. Philips had ample opportunity either to stop using the PE-PUR Foam or to replace the PE-PUR Foam in the Recalled Devices to make them safe and healthy for use by Plaintiffs and members of the Class and State Subclasses but failed to do so.

102. As a direct and proximate result of Philips' breaches of express warranty, Plaintiffs and members of the Class and State Subclasses have been damaged because they did not receive the products as specifically warranted by Philips. Plaintiffs and members of the Class and State Subclasses did not receive the benefit of the bargain and suffered damages at the point of sale stemming from their overpayment for the Recalled Devices.

103. Plaintiffs and the Class and State Subclasses seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their express warranties and resulting breach.

## SECOND CLAIM FOR RELIEF

### BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
### (on behalf of the Nationwide Class or, alternatively, the State Subclasses)

104. Plaintiffs incorporates the foregoing allegations as if fully set forth herein.

105. Philips are merchants engaging in the sale of goods to Plaintiffs and the Class and State Subclasses.

106. There was a sale of goods from Philips to Plaintiffs and the Class and State Subclasses.

107. At all times mentioned herein, Philips manufactured or supplied the Recalled Devices, and prior to the time the Recalled Devices were purchased by Plaintiffs and the Class and State Subclasses, Philips impliedly warranted to them that the Recalled Devices were of merchantable quality, fit for their ordinary use, and conformed to the promises and affirmationsof fact and omissions made on the Recalled Devices' labels and packaging, including that the Recalled Devices were safe and appropriate for human use. Plaintiffs and the Class and State Subclasses relied on Philips' promises and affirmations of fact and omissions when they purchased and usedthe Recalled Devices.

108. Contrary to these representations and warranties, the Recalled Devices were not fit for their ordinary use and did not conform to Philips' affirmations of fact and promises and omissions because use of the Recalled Devices is accompanied by the risk of adverse health effects, which does not conform to the labels and packaging of these devices.

109. Philips breached its implied warranties by selling Recalled Devices that failed to conform to the promises or affirmations of fact made on the packaging or label, as use of each Recalled Devices was accompanied by the risk of developing adverse health effects that do not conform to the packaging or label.

110. Philips was on notice of this breach, as it was made aware of the adverse health effects accompanying use of the Recalled Devices through user reports submitted to Philips and through lab testing.

111. Where relevant, privity exists because Philips impliedly warranted to Plaintiffs and the Class and State Subclasses through the warranting, packaging, advertising, marketing, and labeling that the Recalled Devices were natural, and suitable for use to treat health conditions, and made no mention of the attendant health risks associated with use of the Recalled Devices.

112. As a direct and proximate result of Philips' conduct, Plaintiffs and the Class and State Subclasses have suffered actual damages in that each Recalled Device they purchased is worth less than the price they paid and which they would not have purchased at all had they known of the attendant health risks associated with the use of each Recalled Device.

113. Plaintiffs and the Class and State Subclasses seek actual damages, attorneys' fees, costs, and any other just and proper relief available thereunder for Philips' failure to deliver goods conforming to their implied warranties and resulting breach.

## THIRD CLAIM FOR RELIEF

### FRAUDULENT MISREPRESENTATION
### (on behalf of the Nationwide Class or, alternatively, the State Subclasses)

114. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

115. Philips failed to advise Plaintiffs and the Class and State Subclasses that the Recalled Devices posed serious health risks to their users and Philips falsely represented to Plaintiffs and the Class and State Subclasses that the Recalled Devices were safe for human use.

116. Philips intentionally, knowingly, and recklessly made these misrepresentations and omissions to induce Plaintiffs and the Class and State Subclasses to purchase the Recalled Devices.

117. Philips knew that its representations and omissions about the Recalled Devices were false in that the Recalled Devices contained PE-PUR Foam and thus were at risk of causing adverse health effects to users of the Recalled Devices, which does not conform to the products' labels, packaging, advertising, and statements. Philips knowingly allowed its packaging, labels, advertisements, promotional materials, and websites to intentionally mislead consumers, such as Plaintiffs and the Class and State Subclasses.

118. Plaintiffs and the Class and State Subclasses did in fact rely on these omissions and misrepresentations and purchased and used the Recalled Devices to their detriment. Given the deceptive manner in which Philips advertised, represented, and otherwise promoted the Recalled Devices, Plaintiffs' and the Class and State Subclasses reliance on Philips' omissions and misrepresentations was justifiable.

119. As a direct and proximate result of Philips' conduct, Plaintiffs and the Class and State Subclasses have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known of the health risks, including organ failure and cancer, associated with the use of the Recalled Devices, and (c) which did not conform to the Recalled Devices' labels, packaging, advertising, and statements.

120. Plaintiffs and the Class and State Subclasses seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

## FOURTH CLAIM FOR RELIEF

### FRAUD BY OMISSION
### (on behalf of the Nationwide Class or, alternatively, the State Subclasses)

121. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

122. Philips concealed from and failed to disclose to Plaintiffs and the Class and State Subclasses that use of Recalled Devices is accompanied by a risk of adverse health effects, which does not conform to the products' labels, packaging, advertising, and statements.

123. Philips was under a duty to disclose to Plaintiffs and the Class and State Subclasses the true quality, characteristics, ingredients and suitability of the Recalled Devices because: (a) Philips was in a superior position to know the true state of facts about its products; (b) Philips was in a superior position to know the risks associated with the use of, characteristics of, and suitability of the Recalled Devices for use by individuals; and (c) Philips knew that Plaintiffs and the Class and State Subclasses could not reasonably have been expected to learn or discover prior to purchasing the Recalled Devices that there were misrepresentations and omissions by Philips in the packaging, labels, advertising, and websites regarding the health risks associated with use of these devices.

124. The facts concealed or not disclosed by Philips to Plaintiffs and the Class and State Subclasses were material in that a reasonable consumer would have considered them important when deciding whether to purchase the Recalled Devices.

125. Plaintiffs and the Class and State Subclasses justifiably relied on Philips' omissions to their detriment. The detriment is evident from the true quality, characteristics, and risk

associated with the use of the Recalled Devices, which is inferior when compared to how the Recalled Devices are advertised and represented by Philips.

126. As a direct and proximate result of Philips' conduct, Plaintiffs and the Class and State Subclasses have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known of the health risks associated with the use of the Recalled Devices, and (c) which do not conform to the Recalled Devices' labels, packaging, advertising, and statements.

127. Plaintiffs and the Class and State Subclasses seek actual damages, attorneys' fees, costs,and any other just and proper relief available under the laws.

## FIFTH CLAIM FOR RELIEF

### NEGLIGENT MISREPRESENTATION
### (on behalf of the Nationwide Class or, alternatively, the State Subclasses)

128. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

129. Philips had a duty to Plaintiffs and the Class and State Subclasses to exercise reasonable and ordinary care in the developing, testing, manufacture, marketing, distribution, and sale of the Recalled Devices.

130. Philips breached its duty to Plaintiffs and the Class and State Subclasses by developing, testing, manufacturing, advertising, marketing, distributing, and selling products to Plaintiffs and the Class and State Subclasses that did not have the qualities, characteristics, and suitability for use as advertised by Philips and by failing to promptly remove the Recalled Devices from the marketplace or to take other appropriate remedial action upon becoming aware of the health risks of the Recalled Devices.

131. Philips knew or should have known that the qualities and characteristics of the Recalled Devices were not as advertised or suitable for their intended use and were otherwise not

as warranted and represented by Philips. Specifically, Philips knew or should have known that: (a) the use of the Recalled Devices was accompanied by risk of adverse health effects that do not conform to the packaging and labeling; (b) the Recalled Devices were adulterated, or at risk of being adulterated, by the PE-PUR Foam; and (c) the Recalled Devices were otherwise not as warranted and represented by Philips.

132. As a direct and proximate result of Philips' conduct, Plaintiffs and the Class and State Subclasses have suffered actual damages in that they purchased the Recalled Devices (a) that were worth less than the price they paid, (b) which they would not have purchased at all had they known they contained PE-PUR Foam that could cause users of the Recalled Devices to suffer adverse health effects, and (c) which do not conform to the products' labels, packaging, advertising, and statements.

133. Plaintiffs and the Class and Sate Subclasses seek actual damages, attorneys' fees, costs,and any other just and proper relief available.

## SIXTH CLAIM FOR RELIEF

### UNJUST ENRICHMENT
**(on behalf of the Nationwide Class or, alternatively, the State Subclasses)**

134. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

135. Plaintiffs and the Class and State Subclasses conferred substantial benefits on Philips through their purchase of the Recalled Devices. Philips knowingly and willingly accepted and enjoyed these benefits.

136. Philips either knew or should have known that the payments rendered by Plaintiffs and the Class and State Subclasses were given with the expectation that the Recalled Devices would have the qualities, characteristics, and suitability for use represented and warranted by

Philips. As such, it would be inequitable for Philips to retain the benefit of the payments under these circumstances.

137. Philips' acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Philips to retain the benefits without payment of the value to Plaintiffs and the Class and State Subclasses.

138. Plaintiffs and the Class and State Subclasses are entitled to recover from Philips all amounts wrongfully collected and improperly retained by Defendants, plus interest thereon.

139. Plaintiffs and the Class and State Subclasses seek actual damages, attorneys' fees, costs, and any other just and proper relief available under the laws.

## SEVENTH CLAIM FOR RELIEF

### STATE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAWS
### (on behalf of the Nationwide Class or, alternatively, the State Subclasses)

140. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

141. Defendants' actions were unlawful pursuant to numerous state laws and regulations, including but in no way limited to:

Missouri: Missouri Stat. §§ 407.020 et seq.

Arizona: Arizona Rev. Stat. §§ 44-1522(A) et seq.

California: California Civ. Code §§ 1750 et seq.

Florida: Florida Stat. §§ 501.204 et seq.

Maryland: Maryland Com. Law Code §§ 13-301 et seq.

New Jersey: New Jersey Rev. Stat. §§ 56:8-2 et seq.

Nevada: Nevada Rev. Stat. §§ 598.0915, 598.0923 et seq.

Ohio: Ohio Rev. Code §§ 1345.02 et seq.

Pennsylvania: 73 Pa. Stat. §§ 201-2, 201-3 et seq.

142. For the reasons discussed herein, Philips violated and continues to violate these and similar laws by engaging in the herein described unconscionable, deceptive, unfair acts or practices proscribed by law. Philips' acts and practices, including its material omissions, described herein, were likely to, and did in fact, deceive and mislead members of the public, including consumers acting reasonably under the circumstances, to their detriment.

143. Philips repeatedly advertised on the labels and packing for the Recalled Devices, on Philips' websites, and through national advertising campaigns, among other items, that the Recalled Devices were safe and fit for human use. Philips failed to disclose the material information that the PE-PUR Foam used in the Recalled Devices, and therefore the Recalled Devices themselves, were unsafe and unfit for human use.

144. Philips' representations and omissions were material because they were likely to deceive reasonable consumers to induce them to purchase and use the Recalled Devices without being aware that the PE-PUR Foam used in the Recalled Devices, and therefore the Recalled Devices themselves, were unsafe and unfit for human use. As a direct and proximate result of Philips' unfair and deceptive acts or practices, Plaintiffs and the Class Members and State Subclasses suffered damages by purchasing the Recalled Devices because they would not have purchased the Recalled Devices had they known the truth, and they received a product that was worthless because it contains unsafe PEPUR Foam which can cause a number of adverse health effects, including organ failure and cancer.

145. Philips' deceptive trade practices caused injury in fact and actual damages to Plaintiffs and members of the Class and State Subclasses in the form of the loss or diminishment of value of the Recalled Devices that Plaintiffs and the Class and State Subclasses purchased,

which allowed Defendants to profit at the expense of Plaintiffs and Class Members. The injuries Plaintiffs and Class Members sustained were to legally protected interests. The gravity of the harm of Philips' actions is significant and there is no corresponding benefit to consumers of such conduct.

146. Plaintiffs and Class Members seek all available relief, damages, compensation, awards, costs fees, and other relief for the injuries they have suffered as a result of Defendants' unfair and deceptive acts and practices in contravention of the aforementioned and other applicable consumer protection laws.

## EIGHTH CLAIM FOR RELIEF

### MEDICAL MONITORING
**(on behalf of the Nationwide Class or, alternatively, the State Subclasses)**

147. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

148. At all relevant times, the Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that used them, such as Plaintiffs.

149. Defendants have reported that users of the Recalled Devices face risks of serious injury from the degradation of PE-PUR Foam contained in the Recalled Devices. Degradation of PE-PUR Foam may be caused by exposure to chemical emissions from the foam material, high heat and high humidity environments in certain regions, and cleaning methods such as ozone may accelerate potential degradation.

150. When PE-PUR Foam degrades into particles that may enter the device's pathway and be ingested or inhaled by users of the devices, users face significantly increased risks of serious

injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of degraded foam exposure include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g., kidneys and liver) and toxic carcinogenic effects.

151. The off-gassing of chemicals from the PE-PUR Foam contained in the Recalled Devices poses risks of serious injury that can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. The potential risks of exposure to off-gassing from PE-PUR Foam include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

152. The absence of visible particles does not mean that PE-PUR Foam breakdown has not already begun. Philips has reported that lab analysis of the degraded foam reveals the presence of harmful chemicals including: TDA, TDI, and DEG. TDI is a powerful irritant to the mucous membranes of the eyes and gastrointestinal and respiratory tracts and has been reported to cause Occupational Asthma. Exposure to TDA may result in ataxia, tachycardia, nausea, vomiting, convulsions, and respiratory depression. TDA can cause chemical cyanosis (i.e., bluish discoloration of the skin) by converting hemoglobin to methemoglobin. This compound can also cause fatty degeneration of the liver. TDA and TDI are potential carcinogens. Repeated exposure to DEG has been associated with damage to the kidneys and renal failure.

153. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class have been exposed to substantially increased risks of serious injury from off-gassing and/or degradation of PE-PUR Foam in the Recalled Devices, which is beyond normal background levels of risk.

154. As a direct and proximate result of Defendants' conduct, Plaintiffs and the Class and State Subclasses have a significantly increased risk of suffering serious injury or contracting a serious latent disease and suffering further injury at an unknown date in the future. Such injuries include cancer and organ failure, among others currently unknown or just being discovered.

155. Monitoring procedures exist that makes the early detection of damage from degraded and/or off-gassed PE-PUR Foam possible. These procedures are different from that normally recommended in the absence of the exposure. These monitoring procedures include non-routine surveillance studies, laboratory testing, and physical examinations, and would be reasonably necessary according to contemporary scientific principles.

156. Existing medical research indicates that exposure to TDI, TDA, and DEG, which Philips has found to exist in off-gassed or degraded PE-PUR Foam, can cause serious, life-threatening and permanent injuries. Philips has received reports from users of the Recalled Devices of headache, upper airway irritation, cough, chest pressure and sinus infection. The exposure to the defects inherent in the Recalled Devices has occurred for users, such as Plaintiffs and the Class and State Subclasses, but the full extent of the injuries will not manifest until later in the lives of Plaintiffs and the Class and State Subclasses. Thus, because of Defendants' conduct, it is reasonably necessary that Plaintiffs and the Class and State Subclasses be placed under period diagnostic testing beyond that normally recommended in the absence of use of the Recalled Devices.

157. Plaintiffs demand judgment against Defendants for medical monitoring damages to diagnose injuries caused by the Recalled Devices at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

## VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, prays for judgment against Philips as to each and every count, including:

A. An order certifying this action and the Class and State Subclasses requested herein as a class action, designating Plaintiffs as the representatives of the Class and State Subclasses,and appointing Plaintiffs' counsel as counsel to the Class and State Subclasses;

B. An order declaring that Philips' actions constitute:

i. breach of express warranty;

ii. breach of the implied warranty of merchantability;

iii. fraudulent misrepresentation;

iv. fraud by omission;

v. negligent misrepresentation; and

vi. unfair and deceptive business practices in violation of all applicable consumer protection statutes, and that Philips is liable to Plaintiffs and the Class and State Subclasses, as described herein, for damages arising therefrom;

C. A judgment awarding Plaintiffs and members of the Class and State Subclasses all appropriate damages in an amount to be determined at trial;

D. A judgment awarding Plaintiffs and the Class and State Subclasses medical monitoring damages and/or injunctive relief establishing appropriate medical monitoring for Plaintiffs and the Class and State Subclasses;

E. A judgment awarding Plaintiffs and the Class and State Subclasses prejudgment and post-judgment interest, as permitted by law;

F. A judgment awarding Plaintiffs and the Class and State Subclasses costs and fees, including attorneys' fees, as permitted by law; and

H. Grant such other legal, equitable or further relief as the Court may deem just and proper.

## IX. DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury for all issues so triable.

DATED: September 3, 2021

Respectfully submitted,

*/s/ Inez J. Ross*
James G. Onder #38049
Inez J. Ross #45109
**OnderLaw, LLC**
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# EXHIBIT “A”

# URGENT: Medical Device Recall

## Philips Respironics
## Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during operation.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

| **All Devices manufactured before 26 April 2021, All serial numbers** | |
|---|---|
| Continuous Ventilator | Trilogy 100 |
| | Trilogy 200 |
| | Garbin Plus, Aeris, LifeVent |
| Continuous Ventilator, Minimum Ventilatory Support, Facility Use | A-Series BiPAP Hybrid A30 (not marketed in US) |
| | A-Series BiPAP V30 Auto |
| Continuous Ventilator, Non-life Supporting | A-Series BiPAP A40 |
| | A-Series BiPAP A30 |

**Immediate Actions to be taken by You, the User:**

1. Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.

2. If your physician determines that you must continue using this device, **use an inline bacterial filter.** Consult your Instructions for Use for guidance on installation.

3. Register your device(s) on the recall website www.philips.com/src-update

    a. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
    b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    c. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

**Permanent Corrective Action to be Taken by the Company:**
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

**Other Information:**
If you need any further information or support concerning this recall/issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality and Regulatory
Philips Respironics - Sleep & Respiratory Care

# URGENT: Medical Device Recall

## Philips Respironics
## CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's the air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of Ozone cleaners), and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

| **All Devices manufactured before 26 April 2021, All serial numbers** | |
|---|---|
| Continuous Ventilator, Minimum Ventilatory Support, Facility Use | E30 (Emergency Use Authorization) |
| Continuous Ventilator, Non-life Supporting | DreamStation ASV |
| | DreamStation ST, AVAPS |
| | SystemOne ASV4 |
| | C-Series ASV |
| | C-Series S/T and AVAPS |
| | OmniLab Advanced+ |
| Noncontinuous Ventilator | SystemOne (Q-Series) |
| | DreamStation |
| | DreamStation Go |
| | Dorma 400 |
| | Dorma 500 |
| | REMstar SE Auto |

**Immediate Actions to be taken by You, the User:**

1. Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in this letter.

2. Register your device on the recall website www.philips.com/src-updates
    d. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
    e. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    f. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

**Permanent Corrective Action to be Taken by the Company:**
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

**Other Information:**
If you need any further information or support concerning this issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality and Regulatory
Philips Respironics - Sleep & Respiratory Care

**CERTIFICATE OF SERVICE**

I hereby certify that on September 3, 2021, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this action.

By: /s/ Inez J. Ross
Inez J. Ross